

## REMARKS/ARGUMENT

### **Description of Amendments**

Applicants have amended claims 65-70 and added new defendant claims 81-84 which depend from claims indicated as containing allowable subject matter. Claims 1-17, 24, and 64 are canceled. Accordingly, Claims 18-23, 25-63 and 65-84 remain pending for consideration.

No new matter is introduced by this amendment.

Applicants wish to thank the Office for the indication of allowable subject matter in Claims 19, 43, 46-47, 48, 54, 59-63 and 67-69 as indicated on page 8, paragraph 7 of the Official Action. Although Claim 48 was not included in the list, Applicants understand that the claim, which depends from Claim 47, is also considered to have allowable subject matter.

### **Claim Objections**

On Page 2, paragraph 1 the Official Action asks that the word “end” be added to Claim 70 so that it reads “second end member”. It is unclear to Applicants why the claim should be amended in this way, especially in light of the lack of an antecedent basis for “second end member”. Applicants believe the claim is written in a proper claim format and does not require the suggested change. However, if the Office still believes that such an amendment is needed, the undersigned invites the Examiner to contact him at 414-954-0314 so that the matter can be resolved expeditiously.

Claims 67, 68, and 69 have been rewritten into independent claim format. Removal of the objections to these claims, and allowance is earnestly solicited. Claims 65, 66 and new Claims 81-84 depend from and therefore include all of the limitations of allowable claims 67-69, respectively. Allowance of Claims 65, 66 and 81-84 is earnestly solicited.

### **Rejection under 35 U.S.C. §102**

Claims 27-28, 64-65 and 70-72 stand rejected under 35 U.S.C. §102(e), as being anticipated by *Parson* (US 6,521,284). before addressing the rejections of the independent

claims, Applicants wish to point out that Claim 28 depends from Claim 18. Applicants therefore assume that Claim 28 was not intended to be included in this rejection since it depends from (and therefore includes) all of the limitations of Claim 18, which was not rejected under 35 U.S.C. § 102(e).

Claim 27 is directed to a method of coating a stent, including the steps of positioning a stent on a mounting assembly, wherein a section of the mounting assembly includes a porous surface; and applying a coating composition to the stent, wherein the pores are configured to receive at least some of the coating composition applied to the stent that overflows from the stent during the application of the coating composition, wherein the pores have an open end and a closed end so as to provide a closed pore system on the surface of the mounting assembly.

As best understood, the Official Action has concluded that *Parsons* anticipates Claim 27 because *Parsons* identically discloses, *inter alia*, pores that have “an open end and a closed end so as to provide a closed pore system on the surface of the mounting assembly”. In Applicants previous response, it was established that the through pores of the *Taylor* reference did not anticipate a closed pore system. Even assuming that *Parsons* discloses pores that can hold a portion of the coating substance (as disputed by Applicants in their prior response), those alleged types of openings 12 would clearly amount to through pores, which like *Taylor* do not disclose a closed pore system on the surface of a mounting assembly as described in Claim 27. Accordingly, *Parsons* cannot anticipate Claim 27. Withdrawal of this rejection under 35 U.S.C. § 102(e) is earnestly solicited.

Support for Applicants interpretation for a “closed pore system”, as opposed to an “open pore system”, may be found at paragraph [0031] of Applicants specification.

In the event Applicants’ remarks do not fully address the Office’s concerns over the compliance of Claim 27 with Section 102(e), Applicants respectfully request that the Office please explain its rationale for concluding why *Parsons* teaches a closed pore system as described in Claim 27 and why Applicants’ arguments presented in this and their previous response do not present persuasive evidence to the contrary. As best understood, Applicants find that the Official Action repeats an earlier rejection that was successfully traversed, because there is no explanation given for why *Parsons* discloses a closed pore system but *Taylor* does not.

Claim 70 is directed to a method of coating a stent, including the steps of positioning a stent on a mounting assembly including the step of pinching the stent between a first member and a second member of the mounting assembly, the mounting assembly further including a third member extending through the stent and connecting the first member to the second member; and applying a coating composition to the stent, wherein the third member includes an absorbing layer or is made from an absorbent material that at least partially absorbs some of the coating composition that comes in contact with the third member during the application of the coating composition. Support for the amendments to Claim 70 may be found at paragraph [0028] of U.S. Publication No. 2005/0261764.

*Parsons* describes a body 6 that is placed on ends 4a and 4b, as illustrated in Fig. 1. However, the method of Claim 70 includes the step of positioning a stent on a mounting assembly including the step of pinching the stent between a first member and a second member of the mounting assembly. The structure supports the medical device 6 in *Parsons* not as a result of the step of pinching the medical device between the pieces 4a and 4b. Nor is there any suggestion for a pinching support in this reference. Claim 70 therefore cannot be anticipated by *Parsons* because this reference does not disclose every step described in the claim. Withdrawal of the rejection of, and allowance of Claim 70 is earnestly solicited.

Claims 71-74 depend from, and therefore include all of the limitations of Claim 70. Because Claim 70 contains allowable subject matter, Claims 71-74 are also allowable because they depend from an allowable claim. For at least this reason, withdrawal of the rejections of Claims 71-74 allowance of these claims is earnestly solicited.

Accordingly, Applicants request withdrawal and reconsideration of the rejection of claims 27 and 70-74 under 35 U.S.C. §102, and allowance of these claims.

### **Rejections under 35 U.S.C. §103**

Claims 18, 20-23, 25-26, 29-42, 44-45, 49-53, 55-58 and 76-80

These claims stand rejected under 35 U.S.C. §103(a), as being unpatentable over *Heller* (US 2003/0215564) in view of *Jendersee* (US 5,836,965), *Helfrich* (US 5,308,338) and *Scanlon* (US 2,845,346).

In support of this rejection, the Official Action concludes that one of ordinary skill in the art would have found it obvious to modify *Jendersee*'s balloon expandable stent delivery device retainers (54) so that they are made of a porous material

to enable the catheter with the stent to be used in or out of the body. As taught by *Helfrich* one would have made the retainers of a porous material in order to enable absorption or retention of fluid when the stent is pretreated or enable tissue growth when the device implanted

Official Action at page 7. As best understood, the Office therefore relies on any of the following three rationales for why one of ordinary skill in the art would have modified *Jendersee*'s retainers (54): (1) so that the stent and catheter is enabled for use "in or out of the body"; (2) "in order to enable absorption or retention of fluid when the stent is pretreated"; or to (3) "enable tissue growth when the device implanted". Applicants traverse the rejection under Section 103 for at least the following reasons.

*Jendersee* teaches a stent delivery device for a balloon-expandable stent. The retainers (54) are fixed to the catheter and therefore remain with the catheter following the angioplasty procedure. The stent is used to maintain the vessel wall to prevent restenosis after the balloon has been used to expand the body lumen, i.e., following angioplasty. *See e.g.*, col. 1-2 of *Jendersee*. To leave *Jendersee*'s catheter within the body lumen with the deployed stent, following stent deployment, would invite serious problems caused by reduced blood flow due to the presence of the catheter – the very thing that the angioplasty procedure is intended to cure. The stent delivery device disclosed in *Heller* is of the same variety as *Jendersee*, a balloon-deployable stent and catheter that cannot be left in the body lumen for the same reasons.

*Helfrich*, in contrast, teaches an implantable catheter for peritoneal dialysis. Before this disclosure, these catheter types, intended for being left within a body, used "porous cuffs" for facilitating tissue re-growth for retaining the catheter in place (as opposed to stitching the catheter to the body. *See Col. 1*. A primary purpose of this disclosure is to address the problems of infections especially where the "porous cuffs" are located. *See e.g.*, Col. 2, ll. 61-68. To this end, *Helfrich* forms apertures near the "porous cuffs" so that antiseptic can flow into the cuffs to prevent infection. *See col. 4, ll. 16-46*.

Claim 18 is directed to a method of coating a stent, comprising: positioning a stent on a mounting assembly, wherein a section of the mounting assembly includes a porous surface; and applying a coating composition to the stent, wherein the pores are configured to receive at least some of the coating composition applied to the stent that overflows from the stent during the application of the coating composition, wherein the mounting assembly includes a first member to make contact with a first end of the stent, and a second member to make contact with a second end of the stent, and wherein the pores are located on at least a region of a surface of the first or second member.

As noted above, Applicants understand that three separate rationales (enumerated as (1)-(3) earlier) are advanced by the Office to support its combination of *Jendersee* with *Helfrich*. Each of these rationale will be address separately.

As to rationale (1), it is respectfully asserted that there is no basis for concluding that making *Jendersee*'s retainers (54) porous would enable the stent delivery device to be used inside or outside of the body. To the extent this rationale is intended to mean that *Jendersee*'s balloon expandable stent delivery device would have better or alternative uses outside or inside of the body with porous retainers, or could not be used in both places when the retainers are not porous, Applicants respectfully disagree. There is nothing relevant to *Jendersee*'s device that would be affected if porous retainers (54) were used when the catheter is being used to perform angioplasty or place the stent. The porous cuffs in *Helfrich* are used to promote tissue growth because the catheter in this reference is implanted in the body. Further, The porous cuffs disclosed in *Helfrich* serve no purpose outside the body, as taught by Helfrich. Accordingly, Applicants respectfully submit that the combination of *Helfrich* and *Jendersee* would not have been obvious because a porous retainer "would enable the stent delivery device to be used inside or outside of the body".

Applicants also disagree as to rationale (2). There is no teaching or suggestion in *Helfrich* of a cuff that is porous to "enable absorption or retention of fluid when the stent is pretreated" or that a porous portion of a catheter would serve any purpose under *Jendersee* or *Heller*. As noted earlier, the porous cuffs in *Helfrich* are used to promote tissue growth, not absorb or retain a fluid. Thus, the Office's asserted reason for using a porous cuff is respectfully misplaced (please

see the background and summary of invention of *Helfrich*). Moreover, even if the porous cuffs in *Helfrich* did serve a purpose under *Helfrich* of absorbing or retaining a fluid, the Official Action gives no explanation why this aspect of an implantable catheter would also be used in connection with a balloon-expandable stent delivery device. Accordingly, Applicants respectfully submit that the combination of *Helfrich* and *Jendersee* would not have been obvious under rationale (2) for either of the following two reasons: First, because a porous retainer to “enable absorption or retention of fluid when the stent is pretreated” is not a taught or suggested function of the porous cuff in *Helfrich* (nor has the Office explained how the common knowledge in the art would have provided the motivation in light of *Helfrich*); and second, because the alleged teaching in *Helfrich*’s implantable catheter would have served no useful purpose under *Jendersee* or *Heller* at the time of the invention.

Applicants also disagree as to rationale (3) because as explained above *Jendersee* is not an implantable catheter. Therefore, one of ordinary skill in the art would have had no reason to modify the retainers (54) so that they are porous to “enable tissue growth when the device implanted”.

Accordingly, the Office has advanced what Applicants understood as three separate reasons for why the stated combination of *Jendersee* and *Helfrich* would have been obvious. Applicants have now explained why each of these reasons are not valid reasons for why one of ordinary skill in the art would have had a reason to make *Jendersee*’s retainers porous. Accordingly, without a motivation to combine *Jendersee* and *Helfrich* as required under 35 U.S.C. § 103(a), the Office has not made out a *prima facie* case. For at least this reason, Applicants respectfully request that the rejection of independent Claim 18 be withdrawn and this claim allowed.

Independent Claim 29 is directed to a method of coating a stent, comprising: positioning a stent on a support member, wherein the support member includes an absorbing layer disposed on a surface of the support member; and applying a coating composition to the stent, wherein the absorbing layer is capable of at least partially absorbing some of the coating composition that comes into contact with the absorbing layer during the application of the coating composition, wherein the absorbing layer is in contact with an end of the stent during the application of the

coating composition. For similar reasons to those given above for Claim 18, Applicants respectfully ask that the rejection of Claim 29 also be withdrawn and this Claim allowed.

Independent Claim 34 is directed to a method of coating a stent, comprising: positioning a stent on a support member, wherein the support member includes an absorbent material; and applying a coating composition to the stent, wherein the support member is capable of at least partially absorbing some of the coating composition that comes into contact with the support member during the application of the coating composition, wherein the absorbing material is in contact with an end of the stent during the application of the coating composition. For similar reasons to those given above for Claim 18, Applicants respectfully ask that the rejection of this claim be withdrawn and this claim allowed.

Independent Claim 39 is directed to a method of coating a stent, comprising: positioning a first end of a stent to make contact with a first member of a mounting assembly; positioning a second end of the stent to make contact with a second member of the mounting assembly; and applying a coating composition to the stent, wherein a section of the first or second member includes a porous surface capable of receiving some of the coating composition during the application of the coating composition. For similar reasons to those given above for Claim 18, Applicants respectfully ask that the rejection of this claim be withdrawn and this claim allowed.

Independent Claim 53 is directed to a method of coating a stent, comprising: positioning a first end of a stent so that the first end is supported by a first member of a mounting assembly; positioning a second end of the stent so that the second end is supported by a second member of the mounting assembly; and applying a coating composition to the stent, wherein the first or second member includes cavities capable of receiving and containing at least some of the excess coating composition applied to the stent during the application of the coating composition. For similar reasons to those given above for Claim 18, Applicants respectfully ask that the rejection of this claim be withdrawn and this claim allowed.

Independent Claim 59 is directed to a method of coating a stent, comprising: positioning a first end of a stent so that the first end is supported by a first member of a mounting assembly; positioning a second end of the stent so that the second end is supported by a second member of the mounting assembly; and applying a coating composition to the stent, wherein the first or second member includes a layer disposed on a surface of the first or second member, wherein the

layer absorbs at least some of the coating composition that comes into contact with the layer during the application of the coating composition. For similar reasons to those given above for Claim 18, Applicants respectfully ask that the rejection of this claim be withdrawn and this claim allowed.

Independent Claim 76 is directed to a method of coating a stent, comprising: positioning a stent on a support member, the member including a first member for making contact with a first end of the stent and a second member for making contact with a second end of the stent; and applying a coating composition to the stent, wherein the first or second member is made from an absorbent material capable of at least partially absorbing at least some of the coating composition that comes into contact with the first or second member during the application of the coating composition. For similar reasons to those given above for Claim 18, Applicants respectfully ask that the rejection of this claim be withdrawn and this claim allowed.

Claims 20-23, 25-26, 28, 30-33, 35-38, 40-42, 44-45, 49-52, 55-58 and 77-80 depend from, and therefore include all of the limitations of Claims 18, 29, 34, 39, 53 and 76, respectively. Because Claims 18, 29, 34, 39, 53 and 76 contain allowable subject matter, Claims 20-23, 25-26, 28, 30-33, 35-38, 40-42, 44-45, 49-52, 55-58 and 77-80 are also allowable because they depend from allowable claims. For at least this reason, withdrawal of the rejections of Claims 20-23, 25-26, 28, 30-33, 35-38, 40-42, 44-45, 49-52, 55-58 and 77-80 under 35 U.S.C. § 103(a) and allowance of these claims is earnestly solicited.

If Applicants' foregoing remarks do not fully address the Office's concerns with respect to the requirements for patentability under 35 U.S.C. § 103(a) for Claims 18, 20-23, 25-26, 29-42, 44-45, 49-53, 55-58 and 76-80, Applicants request that the Office please articulate its reasons for sustaining the rejections, including an explanation for why each one of Applicants' reasons for traverse were not sufficient to withdrawal the rejection.

Claims 31-32 and 73-74

These claims stand rejected under 35 U.S.C. §103(a), as being unpatentable over *Parsons* in further view of *Hossainy* (US 6,153,252). Applicants respectfully submit that Claims 31-32 and 73-74 would not have been obvious at least because they depend from claims that are not

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obvious in view of the prior art as discussed earlier. Withdrawal of this rejection, and allowance of these claims is requested.

Accordingly, Applicants request withdrawal and reconsideration of the rejections of the pending claims, and allowance of these claims.

### Conclusion

In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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